Zacks Small-Cap Research

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Resverlogix Corp. (RVX - TSX)

Renal Program Advancing; Financing Options Clarified

Based on our DCF model and a 15% discount rate, RVX is valued at approximately CAD$5.00 per share. Our model applies a 64% probability of apabetalone sales for indications in the BETonMACE trial. Our valuation only includes BETonMACE indication contributions from the US, Europe, & Latin America, as well as royalties from the Hepalink arrangement. It does not recognize potential from renal or other orphan indications.

Current Price (12/15/2016)	$1.71
Valuation	**$5.00**

OUTLOOK

Resverlogix Corp. (RVX.TO) began recruiting and dosing participants in the Phase 3 BETonMACE trial of its lead candidate apabetalone (RVX-208) in high-risk CVD patients with diabetes in November 2015. We believe the trial will take approximately 3 years to complete, targeting topline readout in 2018. With a potential impact on multiple markers for CVD we are optimistic on a materially significant impact on MACE.

The company announced successful PK study results for its Phase 1 renal trial and may commence Phase 2 studies in 1H:17.

At the current price, we view Resverlogix shares as undervalued, and in a position to provide long-term upside potential. We maintain our target price of CAD$5.00 per share and believe that expansion into new geographies, the orphan disease program, and renal disease, could provide further upside to our valuation.

SUMMARY DATA

52-Week High	**2.47**
52-Week Low	**1.10**
One-Year Return (%)	**7.4**
Beta	**0.5**
Average Daily Volume (sh)	**43,739**
Shares Outstanding (mil)	**105.4**
Market Capitalization ($mil)	**185.6**
Short Interest Ratio (days)	**4.26**
Institutional Ownership (%)	**0.0**
Insider Ownership (%)	**42.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2018					$0.0 E
2019					$0.0 E

Earnings per Share

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2016	$0.03 A	-$0.04 A	-$0.08 A	-$0.09 A	-$0.20 A
2017	-$0.06 A	-$0.14 A	-$0.07 E	-$0.06 E	-$0.32 E
2018					-$0.22 E
2018					-$0.23 E

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WHAT'S NEW

Resverlogix Reports Second Quarter Fiscal Year 2017 Results

On December 13, Resverlogix Corp. (TSX: RVX) posted its financial filings for its second quarter of fiscal year 2017 ending October 31, 2016. The company reported no revenues and a net loss of ($15.2)[1] million or ($0.14) per share. This compares to our estimates also of zero revenues and a net loss of ($6.4) million or ($0.06) per share. Total operational expenses for 2Q:17 were $7.6 million, increasing from $4.1 million in the same quarter of the prior year. Second quarter research & development expenses rose 96%, while general & administrative increased 38%. Costs related to the BETonMACE clinical trial and the renal study were the main drivers behind the increase.

Clinical costs totaled approximately $3.6 million with $3.0 million of the total allocated to the BETonMACE clinical trial and $0.3 million for the renal pharmacokinetic clinical trials. This compares to clinical costs of $2.2 million in 2Q:16. Regulatory costs comprised $0.1 million of the total and $0.2 million was spent on other clinical costs including sample analysis, consultants and insurance. Chemistry costs were $1.6 million in the second quarter compared to $0.2 million in in the same quarter of the prior year due to shipment costs of supplies for the BETonMACE trial. Preclinical costs of $0.3 million were up from $0.1 million on higher expenses attributable to various small studies related in part to additional indications. R&D compensation costs were flat year over year at $0.5 million.

General and administrative costs of $1.3 million were up in the second quarter from $0.9 million as a payment for a cardiovascular continuing education grant was made. Net finance costs jumped up in 2Q primarily due to changes in the warrant liability and the fair value of royalty preferred shares. The warrant liability increased due to the increase in stock price at the end of the reporting period and the change in value for the royalty preferred shares was attributable to a rise in the discount rate and changes in other assumptions.

As of October 31, 2016, cash of $12.8 million was held on the balance sheet and long-term debt remained constant sequentially at $47.1 million. Operating cash burn was ($5.7) million in 2Q:17. Cash burn for the quarter, after adjusting for changes in non-cash working capital was ($8.8) million, or approximately ($2.9) million per month. This compares to a ($1.0) million monthly cash burn rate in 2Q:16.

Our Estimates

Resverlogix has increased the pace of investment into its portfolio of indications for apabetalone in recent quarters, launching and completing a Phase 1 PK study with patients suffering from severe renal impairment and accelerating the pace of its BETonMACE study. We anticipate that the company will continue to launch studies in other neighboring indications as funding permits. Due to the rise in research and clinical activity, we have increased our estimates of research and development costs over the forecast period. We maintain our target price of CAD$5.00.

We note that at current cash burn rates, Resverlogix does not have sufficient cash to complete the fiscal year. Management has outlined several financial options that they are currently exploring which we list below:

- Co-development or follow on compounds with major pharmaceutical company would provide upfront payment and coverage of future expenses.
- Licensing on a regional basis would provide upfront payments
- Licensing certain new or orphan indications to partners for upfront payment
- Partnering and offering first right of refusal in an M&A transaction for an upfront payment
- Private placements with equity and warrants
- Public offering of equity, potentially with an IPO on a US Exchange (less likely)
- Debt financing (less likely)

We anticipate that Resverlogix will favor the options in the order they are presented above and expect execution on one or more in the next quarter or two.

[1] Note that financial statements are prepared in US Dollars and our commentary on revenues expenses and earnings is also in US Dollars, while our target price is in Canadian Dollars.

Key Milestones

On May 24, 2016, the company announced the formation of an International Renal Clinical Advisory Board ("RCAB") for the future development of apabetalone into expanded renal indications.

In June 2016, the company announced that a pre-diabetes mellitus study performed by the Baker IDI Heart and Diabetes Institute was published in the journal 'Metabolism' under the title "Effects of the BET-inhibitor, RVX-208 on the HDL lipidome and glucose metabolism in individuals with prediabetes: A randomized controlled trial." The study concluded that apabetalone treatment impacted glucose metabolism and both the reduction in glucose absorption and its production are expected to be of benefit in patients with prediabetes mellitus.

On July 21, 2016, Resverlogix announced that dosing had commenced in a Phase 1 pharmacokinetics ("PK") study with apabetalone in patients with severe renal impairment. This trial has been initiated and designed in accordance with the company's strategy to expand into new indications such as renal and orphan diseases. The primary objective of the Phase 1 study, based in New Zealand, is to determine if apabetalone treated patients with severe renal impairment have the same favorable PK traits as has been illustrated in previous apabetalone trials. Results are expected in the second half of 2016, and if favorable, will likely allow Resverlogix to proceed with more advanced renal impairment and dialysis trials.

On August 11, and December 5, 2016, RVX announced that the independent Data and Safety Monitoring Board (DSMB) for the BETonMACE trial had completed a planned safety review and verbally recommended that the study should continue as planned without any modifications. The DSMB reviewed available study data and noted that no safety or efficacy concerns were identified. The DSMB will conduct additional periodic reviews and will also perform a futility assessment once 125 adjudicated MACE have been observed. The parties remain blinded to the actual safety and efficacy results.

In May and June 2016, new findings were presented at the Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) Scientific Sessions, EAS Congress and the ADA Scientific Sessions. These presentations summarized studies designed to further understand the reductions in MACE observed in apabetalone treated patients.

On August 28, 2016, Resverlogix hosted the symposium, "A novel approach for high CV risk patients with diabetes: The potential of epigenetics" at the ESC Congress. Speakers included renowned experts in the field of CVD presenting a variety of topics related to diabetes, CVD and BET inhibition. A poster was also presented at the congress containing data demonstrating that apabetalone treatment reduced basal and cytokine-induced expression of complement factors in hepatocytes.

The company announced data collection for the Phase 1 pharmacokinetic (PK) study on November 17. The study sought to demonstrate that apabetalone would have the same favorable PK traits for severe renal impairment as it had on other indications in previous trials. Resverlogix plans to proceed with further work on severe renal impairment based on the results which are still under analysis.

A REVIEW OF RESVERLOGIX'S ASSETS

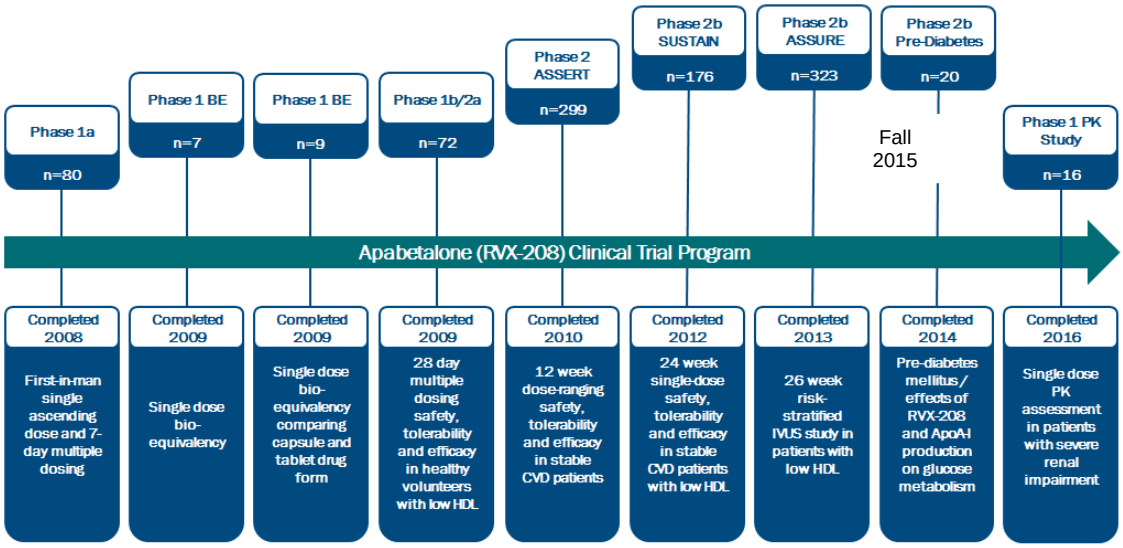
Clinical Overview of Apabetalone

Resverlogix has completed many clinical trials to date. Apabetalone has been tested in over 1,000 patients in 12 countries, and clinical experience with apabetalone has demonstrated that BET inhibitors can be both safe and effective. Over the years, Resverlogix has gathered information from these studies and shifted focus to target patients with low HDL and diabetes with co-treatment of RVX-208 and rosuvastatin (Crestor) and atorvastatin (Lipitor) in its BETonMACE trial.

Prior to the BETonMACE trial, apabetalone has completed two Phase 2b trials named SUSTAIN and ASSURE in collaboration with the Cleveland Clinic. Furthermore, Resverlogix has performed thorough analysis of MACE in the Phase 2b clinical program; 35 MACE events were reported in both the SUSTAIN and ASSURE trials. This analysis demonstrated that treatment with apabetalone was associated with a 55% reduction in MACE. Apabetalone treated patients had a lower level of cumulative events of 6.7% vs. 15.1% (p=0.02) in the placebo treated group.

Furthermore, a beneficial effect of apabetalone on patients with diabetes mellitus was accentuated with a reduction in MACE that was lowered by 77% (p=0.01). BETonMACE will continue to focus on MACE reduction as the primary endpoint for the registration study.

Exhibit I – Summary of Resverlogix's Clinical Trials[2]



Phase 3 "BETonMACE"

In October 2015, Resverlogix launched its Phase 3 "Effect of RVX-208 on Time to Major Adverse Cardiovascular Events in High-Risk Type 2 Diabetes Mellitus Subjects with Coronary Artery Disease" (BETonMACE) trial with lead drug apabetalone in high-risk patients with coronary artery disease (CAD) and type 2 diabetes mellitus (DM). The study is a large international multi-center, double-blind, randomized, parallel group, placebo-controlled clinical trial to determine whether treatment with apabetalone in combination with rosuvastatin or atorvastatin increases the time to MACE compared to treatment with rosuvastatin or atorvastatin alone.

The primary endpoint of the BETonMACE trial is designed to show a relative risk reduction of MACE, narrowly defined as a single composite endpoint of CV death, non-fatal myocardial infarction ("MI") and stroke. The study is an event-based trial and will continue until at least 250 MACE events have occurred. MACE will be adjudicated by an independent committee and the study will be monitored by a data safety monitoring board. The trial is seeking a 30% reduction in MACE as compared to the placebo arm.

Secondary endpoints include time to first occurrence of the composite broad MACE which includes the addition of hospitalization for CVD events (unstable angina and revascularization procedures), changes in lipoprotein

[2] Source: Resverlogix 2Q:17 MD&A

concentrations (HDL and apolipoprotein A-1), changes in diabetes mellitus variables (glucose and glycated hemoglobin), change in alkaline phosphatase ("ALP"), changes in kidney function and additional safety and tolerability of apabetalone.

In order to be eligible to participate in the study, patients must have documented history of type 2 Diabetes Mellitus, experienced a recent (defined as 7-90 days prior to randomization) coronary artery disease ("CAD") event including unstable angina, revascularization procedure or MI and have low levels of HDL (<40 mg/dL for males and <45 mg/dL for females). Standard of care high potency statin therapy shall consist of daily dose of either atorvastatin 40-80 mg or rosuvastatin 20-40 mg. After an initial screening period of 1 to 2 weeks during which subjects will be treated with standard of care statin therapy, subjects will be randomized to either apabetalone 100 mg twice daily or matching placebo with continued statin treatment. This combination treatment period will continue for up to 104 weeks.

Resverlogix believes that the Phase 3 MACE trial may confirm health benefits in CVD, diabetes, and CKD. The main objective of the trial is to confirm MACE reduction by apabetalone as observed in SUSTAIN and ASSURE pooled analysis and also expand safety assessment. The study is conducted in a larger prospective setting with high-risk patients that have diabetes mellitus and low HDL-C (< 40 mg/dL for males and < 45 mg/dL for females who are post events). Management also plans to further explore the potential impact that apabetalone may have on inflammation, the complement and coagulation pathways, vascular calcification, metabolism, and reverse cholesterol transport.

As part of the BETonMACE trial, the study will examine a subset of the patients to test for impact on neuro-degenerative diseases and test for cognition. The subset will include patients over the age of 70 and perform a Montreal Cognitive Assessment (MoCA) test. The company anticipates that this could be from 200 to 300+ participants in the trial. This population group is the equivalent of conducting a Phase 2 dementia trial as part of BETonMACE.

BETonMACE will initially be conducted in Argentina, Mexico and various European cities with expansion into Asia through the partnership with Hepalink. U.S. sites are also a consideration as Resverlogix looks towards FDA approval in this adaptive trial that will target a minimum of 2,400 patients. Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia have already received regulatory approval to open clinical investigator sites and are recruiting patients. The company expects Taiwan to be added to the list of open sites in (calendar year) 1Q:17 through its relationship with Hepalink which will provide a bridge to the eventual registry of the drug in mainland China. Russia will also be added with 20 sites and 200 patients starting in the first calendar quarter of 2017. Based on implied enrollment rates, we think BETonMACE can reach the 1,000 mark by year end 2016.

RVX has also been working with the FDA on adding the United States to the BETonMACE study. Several meetings, including a Type C meeting took place between Resverlogix and the FDA over the late summer and fall. In late fall, the company made the final submission of the required immunotox report which should set things up for a January to March 2017 response from the FDA prior to beginning trials in the United States.

Orphan Disease and Other Programs

On September 24, 2015, Resverlogix announced the commencement of an Orphan Disease Program for Complement Mediated Diseases. The company has also been partnering with universities and leading researchers around the globe for the use of apabetalone in other conditions. Current and ongoing studies include the following alternate indications:

- Neurofibromatosis – Malignant Peripheral Nerve Sheath Tumors (Elephant Man Disease)
- Pulmonary Arterial Hypertension
- Muscular Dystrophy/Facio Scapulo Humeral Dystrophy
- Calciphylaxis/Calcification
- Fabrys Disease
- Neuroinflammation
- Paroxysmal Nocturnal Hemoglobinuria (PNH)

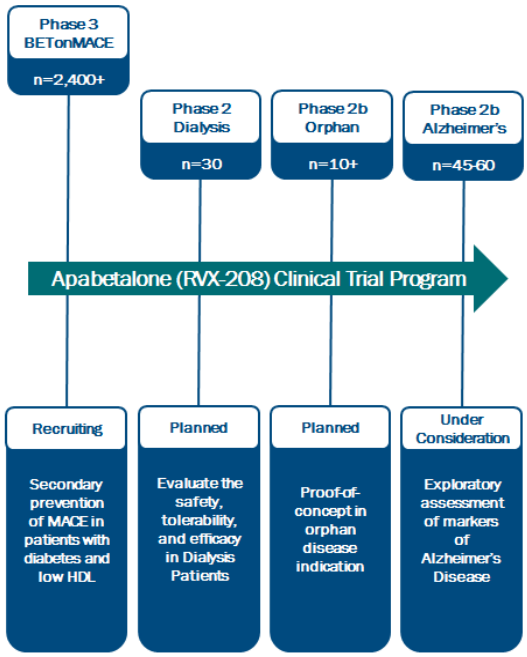
Resverlogix is expanding apabetalone into renal indications. On July 21, 2016, Resverlogix announced that it had begun a Phase 1 pharmacokinetic (PK) trial in patients with severe renal impairment. The study's primary goal is to confirm the favorable pharmacokinetic traits that have been observed in other apabetalone trials. The study is being conducted in New Zealand and completed its data collection in November 2016, after which we expect a Phase 2 trial.

As mentioned above, data for the Phase 1 study has been collected and is currently being analyzed. Concurrently, RVX had been working with the FDA to develop appropriate trial design for the Phase 2 renal study. This will be constructed as a sequential, double-blinded, placebo control, crossover design and is expected to have a duration of 20 to 22 weeks per enrollee. The study will evaluate the safety, tolerability and efficacy of apabetalone in CKD patients on hemodialysis in addition to standard of care. It intends to enroll 30 patients in the United States receiving hemodialysis 3x per week. The investigational new drug application is expected to be filed in 1Q:17.

If maintained on a tight timeline, the Phase 2 trial may generate results by late 2017 to early 2018 followed shortly thereafter by a Phase 3 study. Due to the high number of events seen in high risk dialysis patients, the Phase 3 trial may be sufficiently statistically powered with 1,500 enrollees, which compares to the 2,400 targeted in the BETonMACE trial. If maintained on a strict schedule and enrollment rates are favorable, Phase 3 renal could produce results by late 2019 or 2020.

While we do not currently include a valuation component for a renal indication, we recognize the attractiveness of this pathway and will adjust our model accordingly as development details evolve.

Exhibit II – Current and Planned Clinical Trials



Summary

Resverlogix's lead product candidate, apabetalone, is the first selective BET bromodomain inhibitor in clinical trials for high-risk vascular disease. In the current Phase 3 BETonMACE trial, Apabetalone is targeting a very specific patient population with low HDL, type 2 diabetes mellitus and chronic kidney disease with a high cardiovascular risk for increased MACE. The trial is progressing with patient recruitment and trial site activation in Phase 3 BETonMACE. Currently, all planned countries including Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia have received regulatory approval to open clinical investigator sites and are recruiting patients and sites in Taiwan, China and Russia are expected to launch soon.

As a reminder, our investment thesis for Resverlogix is based on a large and growing underserved market in cardiovascular disease. With a growing older population in the world, and in many cases a less healthy one than in previous generations, the addressable market for therapies that reduce cardiovascular risk is increasing. Apabetalone has shown an ability to positively impact major adverse cardiac events in early trials and we expect the

current BETonMACE trial to confirm this hypothesis. There is also potential for the compound to address a number of other indications, including renal and orphan diseases. With a substantially large market and an anticipated high degree of efficacy, we forecast a rapid uptake of apabetalone following regulatory approval and forecast robust pricing ability given the anticipated pharmacoeconomics of the drug.

We believe that durable patent position and the forecasted pricing of apabetalone, combined with a management skill set surrounding CVD and diabetes and a novel approach to addressing the residual risk in high need CVD patients, support our price target. We highlight that data from the BETonMACE trial will not likely be available until mid to late-2018, but we look forward to see results from the interim futility analysis which will provide a first look after 125 MACE events. The anticipated start of Phase 2 work for renal may provide additional upside, however at this time it is too early to include in our model. We maintain our price target of CAD$5.00 per share.

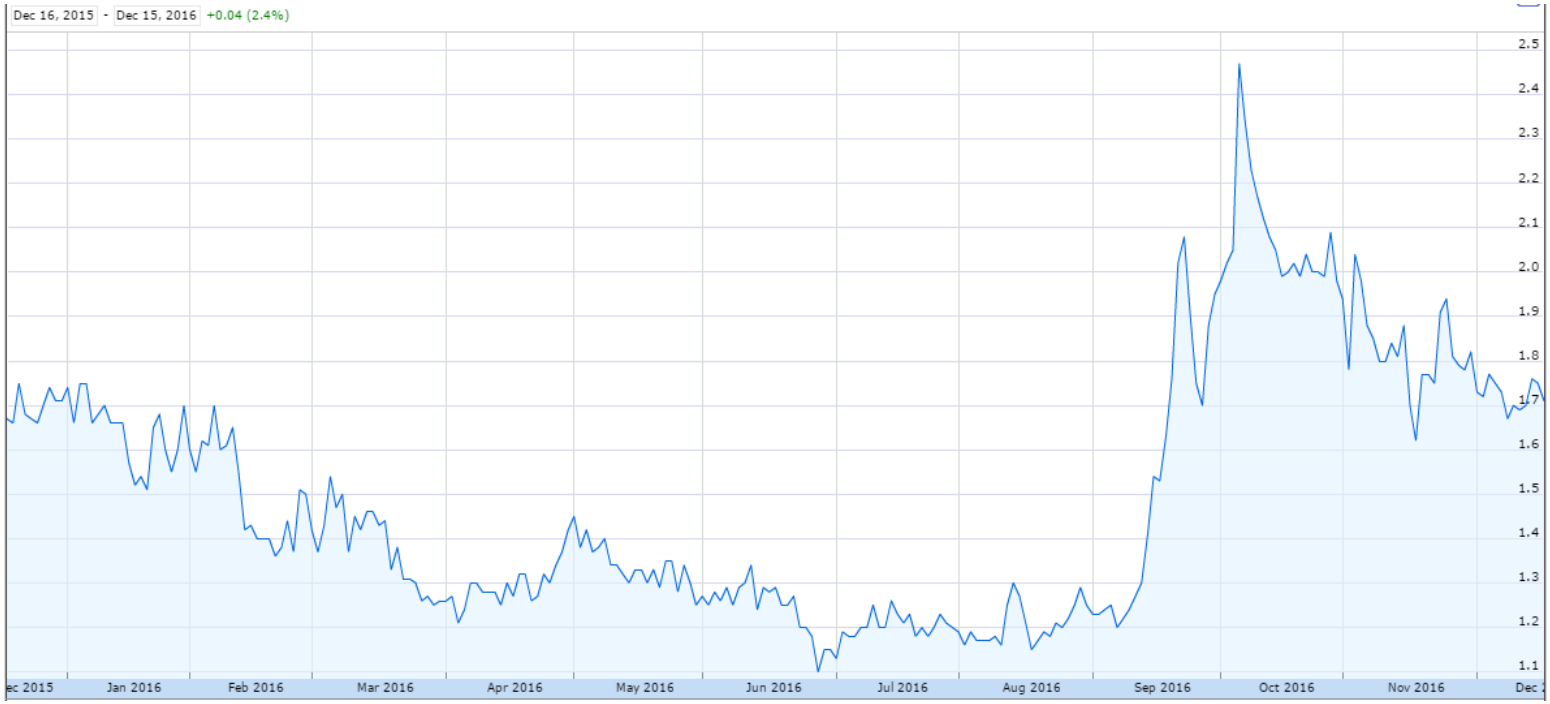
PROJECTED FINANCIALS

Resverlogix Corp. - Income Statement

Resverlogix Corp. (millions of $US)	Apr. 2016 FY-16 A	Jul. 2016 Q1 A	Oct. 2016 Q2 A	Jan. 2017 Q3 A	Apr. 2017 Q4 E	Apr. 2017 FY-17 E	Apr. 2018 FY-18 E	Apr. 2019 FY-19 E
RVX-208	$0	$0	$0	$0	$0	$0	$0	$0
Licensing & Collaborative	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D Expense (net)	$15.7	$6.1	$6.3	$6.0	$6.0	$24.5	$24.0	$25.0
G&A Expense	$4.3	$1.0	$1.3	$1.3	$1.4	$5.0	$5.2	$6.8
Operating Income	($20.0)	($7.1)	($7.6)	($7.3)	($7.4)	($29.5)	($29.2)	($31.8)
Operating Margin	-					-	-	-
Net Finance Activities	$0.3	$0.7	($7.6)	$0.1	$0.1	($6.7)	$0.5	$0.6
Other Gain / (Loss)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.7)	($6.4)	($15.2)	($7.2)	($7.3)	($36.1)	($28.7)	($31.2)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($19.7)	($6.5)	($15.2)	($7.2)	($7.3)	($36.1)	($28.7)	($31.2)
Reported EPS	**($0.20)**	**($0.06)**	**($0.14)**	**($0.07)**	**($0.06)**	**($0.32)**	**($0.22)**	**($0.23)**
YOY Growth						-	-	-
Diluted Shares Outstanding	101.0	106.8	105.3	107.5	130.0	112.4	131.0	135.0

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